



US009254304B2

(12) **United States Patent**
Fulgham

(10) **Patent No.:** **US 9,254,304 B2**
(45) **Date of Patent:** ***Feb. 9, 2016**

(54) **SUPPLEMENT COMPOSITION AND METHODS OF USE**

(71) Applicant: **03 ANIMAL HEALTH, LLC,**
Cleveland, MS (US)

(72) Inventor: **Murray Fulgham,** Cleveland, MS (US)

(73) Assignee: **O3 Animal Health, LLC,** Cleveland,
MS (US)

(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 119 days.

This patent is subject to a terminal dis-
claimer.

(21) Appl. No.: **14/228,242**

(22) Filed: **Mar. 27, 2014**

(65) **Prior Publication Data**

US 2015/0050374 A1 Feb. 19, 2015

Related U.S. Application Data

(63) Continuation-in-part of application No. 13/969,083,
filed on Aug. 16, 2013, now Pat. No. 8,716,331.

(51) **Int. Cl.**

A61K 31/355 (2006.01)
A01N 43/16 (2006.01)
A61K 36/888 (2006.01)
A61K 35/60 (2006.01)
A61K 36/48 (2006.01)
A23L 1/30 (2006.01)
A23K 1/16 (2006.01)
A23K 1/18 (2006.01)
A61K 31/202 (2006.01)
A23K 1/14 (2006.01)

(52) **U.S. Cl.**

CPC **A61K 36/888** (2013.01); **A01N 43/16**
(2013.01); **A23K 1/14** (2013.01); **A23K 1/1603**
(2013.01); **A23K 1/164** (2013.01); **A23K**
1/1646 (2013.01); **A23K 1/1806** (2013.01);
A23K 1/1846 (2013.01); **A23L 1/3002**
(2013.01); **A23L 1/3006** (2013.01); **A61K**
31/202 (2013.01); **A61K 31/355** (2013.01);
A61K 35/60 (2013.01); **A61K 36/48** (2013.01)

(58) **Field of Classification Search**

CPC **A61K 31/355**; **A01N 43/16**
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

8,716,330 B2 * 5/2014 Fulgham **A23L 1/3002**
514/458
8,716,331 B2 * 5/2014 Fulgham **A23K 1/1603**
514/458
8,716,332 B2 * 5/2014 Fulgham **A23K 1/1603**
514/458
2010/0112187 A1 * 5/2010 Crank **A23C 11/103**
426/656
2011/0171187 A1 * 7/2011 Moore **A23L 1/30**
424/93.51

* cited by examiner

Primary Examiner — Yong Chong

(74) *Attorney, Agent, or Firm* — Jeremy A. Smith; Bradley
Arant Boult Cummings LLP

(57) **ABSTRACT**

The present invention relates to a dietary supplement compo-
sition made of: linolenic expeller pressed soybean oil in the
range of 65%-85%, Omega 3 (18/12) fish oil 15%-35%,
1%-20% alpha-tocopherol, and 7.5%-15% acai berry powder
and a method to use this composition to supplement the diet of
a domestic animal, such as a canine or an equine.

5 Claims, No Drawings

1

SUPPLEMENT COMPOSITION AND METHODS OF USE

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. application Ser. No. 13/969,083 filed on Aug. 16, 2013 and now U.S. Pat. No. 8,716,331, which is a continuation of U.S. application Ser. No. 13/012,255 filed on Jan. 24, 2011 and now U.S. Pat. No. 8,536,220, which are hereby incorporated by reference in their entirety.

This application is related to U.S. provisional patent application Ser. No. 61/298,260 (hereby incorporated by reference in its entirety) filed Jan. 26, 2010 through U.S. application Ser. No. 13/012,255. This application is related to U.S. application Ser. Nos. 13/969,057 and 13/969,124, filed concurrently with application 13/969,083.

FIELD OF THE INVENTION

The present invention is related to an animal nutritional supplement and, more particularly to a method of using an equine nutritional supplement to alleviate chronic or acute conditions in domestic animals such as equines and canines.

BACKGROUND OF THE INVENTION

Equines are known to suffer from a number of conditions related to vitamin and minerals deficiencies due to poor quality forage or hay, chronic colic, chronic diarrhea, or anorexia resulting from dental disease. In addition, there may also be disturbances in absorption as the result of liver or biliary tract disease, hypothyroidism, anemia and other pathological conditions of the digestive system and related organs. Numerous equine supplements are currently on the market. Some of these supplements include various Omega 3 products. The Omega 3 is from a variety of sources, strengths, and types of Omega 3 that supply EPA, DHA or ALA for supplementation of the equine diet. Some are from marine oils such as fish oil which contain different amounts of DHA and EPA, the long chain Omega 3s, depending on which fish and which part of the ocean they came from. Some come from vegetable oils such as soybean oil, canola oil, or flax seed, all of which contain ALA Omega 3, the parent chain of Omega 3. However, the equine diet in the wild provides a balance of Omega 3, Omega 6 and Omega 9. Domestic animals feeds may disturb this balance and result in chronic or acute conditions.

SUMMARY OF THE INVENTION

Thus, it is a purpose of the present invention to provide a nutritional supplement for alleviating various chronic or acute conditions in domestic animals associated with an imbalance of Omega 3, Omega 6 and Omega 9. It is also a purpose of the present invention to provide a method of use for the nutritional supplement, of the present invention, to alleviate chronic or acute conditions in domestic animals.

In accordance with a preferred embodiment of the invention, an equine nutritional supplement for improving omega balance in domestic animals is made of: a balance of Omega 3, Omega 6, and Omega 9 plus other nutrients, including from the acai berry, in expeller pressed soybean oil. More specifically, this composition is made of: linolenic expeller pressed soybean oil in a volume range of 65%-85%, Omega 3 fish oil in the range of 15%-35%, and 1%-20% alpha-tocopherol (natural vitamin E). This invention further provides a method

2

for alleviating chronic or acute conditions in animals by the method of administering a nutritional supplement to the animal.

This invention more specially provides a method for alleviating anhidrosis in an equine, especially when the equine has been non-responsive to other treatment methods and compositions. This method involves administering a nutritional supplement composition made of 3:1 omega 6 to omega 3, 12,000 IU per serving of alpha-tocopherol, and 7.5% to 15% (total by weight) of acai berry.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a nutritional supplement to balance the distribution of Omega 3s, Omega 6s, and Omega 9 in the diet of a domestic animal. The present invention relates to a composition made of: linolenic expeller pressed soybean oil in the range of 65%-85%, Omega 3 fish oil in the range of 15%-35%, and 1%-20% alpha-tocopherol (natural vitamin E). In the preferred embodiment, the fish oil is 18/12. More specifically, the parent chain (ALA) of Omega 3s from natural expeller pressed soy oil and the long chain Omega 3s (DHA and EPA) from natural Omega 3 fish oil and natural alpha-tocopherol (vitamin E) are provided. The alpha-tocopherol has a dual role in providing the needed additional vitamin E and acting as a preservative for this composition. The alpha-tocopherol is in a concentration from between 3,000 to 28,000 IU per serving.

Linolenic expeller pressed soybean oil is made by mechanical (expeller) extraction. During mechanical extraction, an expeller press crushes the soybeans to extract the oil. This pressing is done under intense pressure, and raises the temperature of the oil to 185 to 200° F. (85-93.3° C.). Typically, the soybeans are heated up to 250° F. (120° C.) before being placed in the expeller. Alternatively, the linolenic expeller pressed soybean oil can be cold pressed using filtration and distilled water to filter the oil.

The linolenic expeller pressed soybean oil is admixed with the fish oil and alpha-tocopherol in the volume range of 65%-85%, Omega 3 (18/12) fish oil in the range of 15%-35%, and 1%-20% alpha-tocopherol (natural vitamin E) to form the supplement composition of the present invention.

Bulk Fish Oil comes in two general varieties: 18% EPA, 12% DHA and 30%. Both refer to the general level of omega-3 in the oil. In 18/12 the levels of EPA and DHA are set in the specifications to 18% EPA and 12% DHA. In what is generally considered a lower grade (30% fish oil) the levels of EPA and DHA are not specified and therefore, depending on seasonal variations.

The animal nutritional supplement can be used for improving or alleviating various chronic or acute conditions in equine or canines associated with an imbalance of Omega 3, Omega 6 and Omega 9. The use of the supplement composition has been show to provide: a healthy digestive system, reduces inflammation in the joints, blocks lactic acid buildup in muscles, increases blood flow to all organs and joints promotes beautiful hair coats and healthy hooves, builds a strong immune system and promotes a healthy reproductive system. The serving size of the present composition for an average horse is 4 ounces daily (1 oz. per 300 lbs.). It is dispensed directly onto feed. If the horse is fed twice daily the dosage can be applied either in one feeding or divided in two and given at both feedings. Serving size can be increased for horses with specific needs or problems. For example, it is recommended to double the dosage a few days prior to competition for show horses to enhance coat bloom, respiration, and recovery from the extra work and stress of the show. The

3

composition can be formulated as an equine top dress liquid mixture by packaging the liquid product in a gallon container. In one embodiment, the composition is made from ingredients that have been produced using methods of organic farming or may be certified as being organic.

In an alternative embodiment, the composition can be provided as an additive to an equine feed. In another embodiment, the supplement composition can be prepared as a solid supplement. In this embodiment, the supplement composition can be blended with inactive ingredients such as: natural soy lecithin, apple pectin, calcium carbonate, dicalcium phosphate, citric acid, flavoring, anise oil, primary yeast dehydrated, silicon dioxide, yeast extract, yeast fermentation solubles, vegetable stearate, and lignin sulfate. The inactive ingredients can be added to the extent they do not change the fundamental properties of the supplement composition. The solid supplement composition can be formulated into pellets according to techniques known to those skilled in the art.

In an alternative embodiment, a nutritional supplement composition is made of linolenic expeller pressed soybean oil to Omega 3 fish oil in a ratio of 3:1 and alpha-tocopherol (natural vitamin E). Sufficient alpha-tocopherol is added to the mixture to provide 12,000 IU per serving of alpha-tocopherol. This nutritional supplement composition can be used to treat anhidrosis in equines. Equine anhidrosis is the inability in a horse to sweat due to intolerance to heat and humidity. It is estimated that 20%-30% of horses in southern regions suffer sweat disorders (anhidrosis). Horses raised in cool climates and later transferred to very warm southern or tropical areas are prone to this illness.

In yet another alternative embodiment, a nutritional supplement composition is made of linolenic expeller pressed soybean oil, Omega 3 fish oil, and alpha-tocopherol (natural vitamin E) as described in the various embodiments above, with the addition of 7.5% to 15% by weight of acai berry. The acai berry may be from any source, but preferably the acai berry is a freeze-dried powder from an organic source. In the preferred formulation, the composition is made with linolenic expeller pressed soybean oil in the volume range of 65%-85%, Omega 3 fish oil 15%-35%, 1%-20% alpha-tocopherol. The preferred formulation also contains two (2) cups of freeze-dried organic acai berry powder per gallon of the soybean oil, Omega 3 fish oil, and alpha-tocopherol mixture. Other formulations using the teachings above may also be used with the acai berry composition.

The acai berry composition should be mixed well before being applied as a top dressing. No emulsifier is necessary, but any acceptable emulsifier known in the nutritional supplement field may be used. The acai berry composition serving size for an average horse is 4 ounces daily (1 oz. per 300 lbs.). It may be dispensed directly onto feed as a top dressing composition. If the horse is fed twice daily the dosage can be applied either in one feeding or divided in two and given at both feedings. Serving size can be increased for horses with specific needs or problems, or as a loading regimen by giving the horse three times the dosing serving size for the first 1-3 days.

EXAMPLE 1

Equine A, a 2 yr. old western pleasure horse, received four oz. of the composition on a daily basis for eight weeks. After receiving the supplement, it was observed that equine A was quieter and more focused on his training than ever before. The weight gain and bloom within the first month were incredible. Equine B a young horse with early onset of arthritis received the composition for its anti-inflammatory benefits. It was

4

reported by the attending veterinarian that the product added weight and bloom on horses quickly and did not affect their energy levels, in contrast to prior supplements.

EXAMPLE 2

In August, 2010, Equine C could barely stand due to pain. The horse was diagnosed with navicular syndrome, i.e., heel soreness or lameness. With this condition, some horses may be sound with large structural navicular changes whereas others may be extremely lame with minimal radiographic changes. The most commonly seen changes are enlarged blood vessel channels, "lollipop lesions", spurring, tiny fractures off the navicular edge, cystic or lytic areas within the bone, and erosion of the contact area between the navicular bone and deep digital flexor tendon. Equine C was treated with four oz. of the composition on a daily basis for 12 weeks crossed with the Acuscope/Myoscope treatments. Equine C has been pain free for over one year without injections or other interventions.

EXAMPLE 3

Four oz. of the alternate composition of this invention was given on a daily basis to Equine group D for anhidrosis for 60 days. An immediate improvement in the ability to sweat was observed. Additionally, the overall condition of Equine group D improved within a few short weeks. The improvements in condition included reduced swelling, the ability to hold their weight better and their hooves and hair coats seemed to have improved as well.

EXAMPLE 4

Canine A was misdiagnosed with allergies in early June of 2010, and the treatment of antibiotics and steroids sent her into a severe downward spiral. Her condition was diagnosed as Demodex mange, which all puppies carry from their mothers at birth. A healthy immune system keeps puppies from having trouble with these mites. Her immune system was basically shut down from the treatment. Her condition worsened. Her skin was red, and hair was falling out. Canine A was treated with IMMUNOPLEX®, derma support herbal remedies and the present composition at 0.5 ounce per day. Within a week, whiskers of hair appeared and her hair and skin were restored to normal. Canine A has received the treatment continuously since to maintain healthy skin and coat.

EXAMPLE 5

Equine E was a bottle fed horse experiencing significant trouble with gaining and maintaining weight. Equine E's regular feed was supplemented with about 1 oz. of the composition on a daily basis for one week, then increased dosage to 4 oz. of the composition per day. Within three days Equine E's coat showed signs of improvement in coat bloom. After the initial week, Equine E began to increase weight gain, which he was able to maintain unlike before using the composition despite decreasing his rations. Equine E's muscle tone has also shown dramatic improvement, which demonstrates that the composition is not leading to "bad" weight gain in the horse.

EXAMPLE 6

Equine F, a three year old gelding, was experiencing locking up in his stifle joints. Stifle blistering was performed

5

without success. Before resorting to surgery, Equine F was put on a regimen of 3 oz. of the composition three times per day for 15 days. After 15 days of the supplement composition, Equine F is no longer experiencing locking up. Equine F also was suffering from colic, and while on the same regimen showed faster recovery from the digestive blockage (colic). Equine F continues to be colic free and no longer has issues with stifle joint lock up.

EXAMPLE 7

Equine G, a mare, was suffering from a hock injury that caused considerable lameness, which kept her from being shown. The mare has been treated with four oz. of the composition daily for over three months. The swelling in Equine G's hind leg has completely decreased after being put on the daily regimen of the composition, and her step and reach continues to improve such that her owner is considering showing the horse in the near future.

EXAMPLE 8

Equine H is a western pleasure horse that had been experiencing anhidrosis. Equine H was treated with four oz. of the anhidrosis formula of the composition daily for one month, then given the supplement composition at the same dosage regimen for five months. Equine H's anhidrosis quickly was alleviated, and also showed great improvement in coat bloom and weight gain. The rations for Equine H were decreased due to the maintenance of the weight gain. Equine H also experienced dramatic improvements in hoof health, no longer showing chips and growing faster.

EXAMPLE 9

Equine group I is a group of horses that were suffering from joint swelling/pain. Each was given four oz. of the composition added to their feed daily for at least two months. All were reported to have experienced and maintained decreased swelling and pain in their joints, in addition to decreased muscle soreness after working.

6

While the invention has been described with respect to a limited number of embodiments, those skilled in the art, having benefit of this disclosure, will appreciate that other embodiments can be devised which do not depart from the scope of the invention as disclosed herein. Accordingly, the scope of the invention should be limited only by the attached claims.

EXAMPLE 10

Equine group J is a group of Thoroughbred horses that were suffering from anhidrosis. They did not respond to the formulations disclosed that did not contain acai berry. However, after receiving the acai berry formulation containing 2 cups of freeze dried organic acai berry powder for as few as one day began to sweat normally.

Although the present invention has been described and illustrated with respect to a preferred embodiment and a preferred use thereof, it is not to be so limited since modifications and changes can be made therein which are within the full intended scope of the invention.

I claim:

1. A method for alleviating anhidrosis in a domestic animal, the method comprising administering a nutritional supplement to said domestic animal, the nutritional supplement consisting of linolenic expeller pressed soybean oil in the volume range of 65%-85%, Omega 3 fish oil 15%-35%, 1%-20% alpha tocopherol (natural vitamin E), and 7.5%-15% by weight of acai berry powder as the only active ingredients in the nutritional supplement.

2. The method of claim 1, wherein the domestic animal is an equine.

3. The method of claim 2, wherein 1 oz. of said nutritional supplement is administered per 300 lbs of said equine per day.

4. The method of claim 3, wherein the concentration of alpha-tocopherol ranges from 3,000-28,000 IU per day.

5. The method of claim 1, wherein the acai berry powder is from an organic source.

* * * * *